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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
	8

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/11/00.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 & 16-19 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-8 & 16-19 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Claim 5 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 5 claims retention of >90% activity under certain conditions at 25°C and <90% activity at 30°C. There is apparently no teaching of the activity of the enzyme under these conditions in the instant specification. This rejection was not addressed in the instant amendment and so is repeated.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mitsugi, et al. (A) or Boyer, et al. (B or C). Mitsugi, et al. teach an alpha amylase from *Bacillus subtilis* AJ-3255

that has an optimal pH of 9 at 40°C and is effective between pH 6 and 11 at 40°C (column 3, lines 47-53). Boyer, et al. (B) teach an alpha amylase from a new species of *Bacillus* (column 1, lines 30-32) that has a "maximum activity at pH 9 to pH 9.2 and at about 50°C" (column 4, lines 24-25). Boyer, et al. (C) teach a amylase with a pH optima of 9.2, *Bacillus species* B-3881. It is maintained that these enzymes are the enzyme of the instant claims, absent very convincing proof to the contrary. This rejection is repeated for the reasons given in the previous action. Applicant's arguments have been carefully considered but are not considered adequate to overcome the instant rejection.

Applicants simply allege that they "have discovered a new class of α-amylases that are distinct from previously known α-amylases in terms of their amino acid sequence and properties" and that the "Examiner is merely speculating that the presently claimed enzymes are identical to those disclosed in the cited reference" and that "it is Applicants' position that the presently claimed enzymes are patentably distinct from the" enzymes of the cited reference. No further argument or evidence of this is offered.

In re Best, Bolton and Shaw 195 USPQ 430, 433 (CCPA 1977) state that "Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product". *In re Brown and Safer* 173 USPQ 685, 688 (CCPA 1972) state that "We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a

product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of process put before it and then obtain prior art products and make physical comparisons therewith." The examiner has rejected the claims as being anticipated or obvious over three references that appear *prima facie* to be the enzyme of the instant claims and given reason why he has so concluded. Therefor the burden of proof shifts to the applicants to disprove this and they have not done so.

Claims 8 and 17-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mitsugi, et al. (A) or Boyer, et al. (B or C). This rejection has not been separately argued from the 35 U.S.C. § 102(b) rejection, which argument has been addressed *infra*.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., Ph.D. whose telephone number is (703) 308-1834. The examiner can normally be reached on any day of the week from 7:30 AM until 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Patterson
December 1, 2000

CHARLES L. PATTERSON, JR.
PRIMARY EXAMINER
GROUP 1800